PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 45.171 CURRA	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IT 03/00331	International filing date *(day/month/year)* 29.05.2003	Priority date *(day/month/year)* 29.05.2003
International Patent Classification (IPC) or both national classification and IPC A61F2/36		
Applicant CURRADINI, Giorgio E.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29.12.2004	06.09.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Josten, S Telephone No. +49 89 2399-2338

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT 03/00331

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-11 received on 08.08.2005 with letter of 05.08.2005

Drawings, Sheets

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 3

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 3

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1,2,4-11
Industrial applicability (IA)	Yes:	Claims	1,2 4-11
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The following documents have been cited in the Search Report:

   D1: EP-A-0 669 116 (ARTOS MED PRODUKTE) 30 August 1995 (1995-08-30)
   D2: FR-A-2 681 239 (COLLOMB JEAN ;IMPACT (FR); MAJOU CLAUDE (FR)) 19 March 1993 (1993-03-19)
   D3: EP-A-0 354 142 (BASCOULERGUE GERARD ;DEBIESSE JEAN LOUIS (FR); BASSO MAURICE (FR);) 7 February 1990 (1990-02-07)
   D4: DE 44 37 479 A (ECHTERMEYER VOLKER PROF DR) 2 May 1996 (1996-05-02)

2. With letter of 05.08.05 the applicant has proved the existence of the word "mixtilinear" by referring to the "Brainy Dictionary". Thus, the objection raised in the Written Opinion is no longer maintained and the word "mixtilinear" is accepted and should be used in the future.

3. Claim 1 is not novel over the **D1** which discloses (see Figures 1 to 3) a femoral stem 1 for a hip prosthesis comprising:
   - a main body 2 with mainly longitudinal development and a with a generally wedge shape, adapted to be inserted into the femoral canal present in the body of the femur;
   - a central body of a generally trapezoidal shape integral with said main body, adapted to be located in the proximal zone of said femur;
   - an appendix projecting from said central body, provided with a terminal pin adapted to receive a spherical head of joint in the cotyle belonging to said prosthesis and inserted in the acetabuly zone of the pelvic bone,

   said main body and said central body are defined by a shaped surface on one side (see the surface on the medial side of the shaft in Figure 2 of **D1**) and by a surface consisting of differnt kinds of lines on the opposite side (see the surface on the lateral side of the shaft in Figure 2), **wherein** a shaped notch 6.1 is present in said central body, said notch 6.1 starting from the surface (i.e. the surface consisting of different kinds of lines = the surface on the lateral side of the shaft) of the main body and

extending upwards transversally in respect of the longitudinal extension (see Figure 2) of said main body up to the proximity of said projecting appendix.

Thus, all the features of present claim 1 are known from **D1** and the claim, therefore, does not meet the requirements of Article 33(2) PCT.

Reference is made to the fact, that the features of present claim 1 are also known from **D2** (see Figures 1 to 3) and from **D3** (see Figures 1 and 2).

4. Dependent claims 2 and 4 to 11 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Articles 33(2) and 33(3) PCT) since they relate to slight constructional changes of the femoral stem known from **D1**, **D2** or **D3** which come within the scope of the customary practice followed by persons skilled in the art.

5. Claim 1 is not clear (Article 6 PCT) as to the wording "from the surface (7)" (see line 17) since the reference numeral 7 has no limiting effect. Said wording should have been amended to read "from the surface consisting of different kinds of lines (7)" or "from the mixtilinear surface (7)" (see the above-mentioned paragraph 2).

In addition, claim 1 should have been clarified by replacing the wording "on one side" by the wording "on the medial side", by replacing the wording "on the opposite side" by the wording "on the opposite lateral side" and by introducing the wording into claim 1 that the shaped noth (8) passes through the thickness of said central body (3; 101) from the anterior side up to the posterior side of the stem (i.e. a clarified wording of present claim 3 which in its unclear form had not been searched).

Further, for the same reasons of clarity the wording "extending upwards transversally in respect of the longitudinally extension of said main body (2) up to the proximity of the projecting appendix" should have been replaced by the originally filed wording "extending up to the proximity of said projecting appendix".

CLAIMS

1) A femoral stem (1; 100) for hip (A) prosthesis (R) comprising:

- a main body (2) with mainly longitudinal development and with a generally wedge shape, adapted to be inserted into the femoral canal (N) present in the body (C) of the femur (F);
- a central body (3; 101) of a generally trapezoidal shape integral with said main body (2), adapted to be located in the proximal zone (Z) of said femur (F);
- an appendix (4) projecting from said central body (3; 101), provided with a terminal pin (5) adapted to receive a spherical head (S) of joint in the cotyle (I) belonging to said prosthesis (R) and inserted in the acetabular zone (E) of the pelvic bone (O),

said main body (2) and said central body (3; 101) being defined by a shaped surface (6) on one side and by a surface consisting of different kinds of lines (7; 102) on the opposite side, ***characterized in that*** *a shaped notch (8) is present in said central body (3), said notch (8) starting from the surface (7) of said main body (2) and extending upwards transversally in respect of the longitudinal extension of said main body (2) up to the proximity of the projecting appendix (4).*

2) The femoral stem (1; 100) according to claim 1) **characterized in that** said shaped notch (8) consists of a concave-convex continuous surface (8a) defining a profile (8') having generally the shape of a *half-slot.*

3) The femoral stem (1; 100) according to claim 1) **characterized in that** said shaped notch (8) passes through the thickness of said central body (3; 101).

4) The femoral stem (1; 100) according to claim 1) **characterized in that** said *surface consisting of different kinds of lines* (7; 102) consists of a first generally straight surface (7a; 102a) belonging to said central body (3; 101) and a second generally straight surface (7b) belonging to said main body (2), connected to said first surface (7a; 102a) through a generally convex radiused zone (7c) from which said shaped notch (8) is starting.

5) The femoral stem (1; 100) according to claim *4)* **characterized in that** the extension of said second surface (7b) defines with

said first surface (7a; 102a) an acute angle (α).

6) The femoral stem (1; 100) according to claim *4)* **characterized in that** said shaped notch (8) divides said central body (3; 101) into a first zone (3a; 101a) arranged generally facing the greater trochanter (G) of said femur (F) and second zone (3b; 101b) arranged generally facing the lesser trochanter (P) of said femur (F), said first zone (3a; 101a) and said second zone (3b; 101b) being connected to each other through a bridge (3c) comprised between said shaped notch (8) and the radiused surface (9) between said projecting appendix (4) and said *surface consisting of different kinds of lines* (7; 102).

7) The femoral stem (1; 100) according to claim *6)* **characterized in that** said profile (8') consists of a first stretch (8b) connected to said *surface consisting of different kinds of lines* (7; 102) with a generally constant cross section, and a second stretch (8c) extending until *below* said bridge (3c) with a widened cross section.

8) The femoral stem (100) according to claim *6)* **characterized in that** said first zone (101a) of said central body (101) is externally provided with at least a longitudinal fin (103, 104) generally developed for the entire length (L_1) of said first zone (101a).

9) The femoral stem (100) according to claim 8) **characterized in that** said fin (103, 104) is arranged along a longitudinal axis (Y, Y') generally parallel to said first surface (102a) of said *surface consisting of different kinds of lines* (102).

10) The femoral stem (100) according to claim 8) **characterized in that** said fin (103, 104) has a cross sectional conical profile (103', 104').

11) The femoral stem (1; 100) according to claim 1) **characterized in that** said shaped surface (6) has a concave-convex *profile in longitudinal section*.